

CLAIMS

1 1. A method for evaluating a clinical trial protocol, comprising the steps of:
2 encoding workflow tasks of a clinical trial protocol into a database that includes data
3 objects describing protocol events and relationships among protocol events;
4 identifying an operational uncertainty in said protocol during said step of encoding;
5 associating said uncertainty with at least a particular one of said objects in said database;
6 and
7 in dependence upon said objects in said database, displaying a graphical-visual
8 representation of said protocol, said graphical-visual representation including a human-
9 perceptible indication that said particular object has an operational uncertainty associated
10 therewith.

1 2. A method according to claim 1, wherein said database is an object-oriented
2 database.

1 3. A method according to claim 1, wherein said data objects include protocol event
2 objects describing protocol events, and temporal constraint objects describing temporal
3 constraints among said protocol event objects.

1 4. A method according to claim 3, wherein said step of displaying comprises the
2 step of displaying each of said data objects in a color which differs depending on whether an
3 operational uncertainty is associated therewith.

1 5. A method according to claim 1, wherein said step of displaying comprises the
2 step of displaying each of said data objects in a color which differs depending on whether an
3 operational uncertainty is associated therewith.

1 6. A method according to claim 1, wherein said operational uncertainty comprises
2 an inconsistency in said protocol.

1 7. A method according to claim 1, wherein said operational uncertainty comprises
2 an insufficiently specified parameter in said protocol.

1 8. A method according to claim 1, wherein said operational uncertainty comprises
2 an omitted parameter in said protocol.

1 9. A method according to claim 1, wherein said operational uncertainty concerns a
2 temporal constraint among at least two of said protocol events.

1 10. At least one computer readable medium collectively carrying a machine readable
2 database which includes protocol data objects describing events of a clinical trial protocol and
3 relationships among protocol events of the clinical trial protocol, said database further including
4 a disambiguation comment object which identifies an operational uncertainty in said protocol,
5 said disambiguation comment object being associated with at least a particular one of said
6 objects in said database.

1 11. A medium according to claim 10, wherein said database is an object-oriented
2 database.

1 12. A medium according to claim 10, wherein said data objects include protocol
2 event objects describing protocol events, and temporal constraint objects describing temporal
3 constraints among said protocol event objects.

1 13. A medium according to claim 12, wherein said disambiguation comment object is
2 associated with one of said protocol event objects.

1 14. A medium according to claim 12, wherein said disambiguation comment object is
2 associated with a particular one of said temporal constraint objects.

1 15. A medium according to claim 14, wherein said operational uncertainty concerns
2 the amount of time allowed to elapse between two protocol events identified by said particular
3 temporal constraint object.

1 16. A medium according to claim 12, wherein said data objects further include
2 workflow task objects.

1 17. A medium according to claim 16, wherein each of said workflow task objects is
2 associated with at least one of said protocol event objects.

1 18. A medium according to claim 16, wherein said disambiguation comment object is
2 associated with one of said workflow task objects.

1 19. A medium according to claim 10, wherein said operational uncertainty comprises
2 an inconsistency in said protocol.

1 20. A medium according to claim 10, wherein said operational uncertainty comprises
2 an insufficiently specified parameter in said protocol.

1 21. A medium according to claim 10, wherein said operational uncertainty comprises
2 an omitted parameter in said protocol.

1 22. A medium according to claim 10, wherein said operational uncertainty concerns
2 the amount of time allowed to elapse between two of said protocol events.

1 23. At least one computer readable medium collectively carrying a machine readable
2 database which includes protocol event objects describing events of a clinical trial protocol and
3 temporal constraint objects describing temporal relationships among said protocol event objects,
4 at least a particular one of said temporal constraint objects identifying an amount of time
5 between at least two of said protocol events.

1 24. A medium according to claim 23, wherein said database is an object-oriented
2 database.

1 25. A medium according to claim 23, wherein said database further includes
2 workflow task objects.

1 26. A medium according to claim 23, wherein said amount of time describes the time
2 that a hypothetical patient is expected to take between first and second identified ones of said
3 protocol event objects.

1 27. A medium according to claim 23, wherein said particular temporal constraint
2 object identifies said amount of time by identifying at least one member of the group consisting
3 of minimum and maximum times.

1 28. A medium according to claim 27, wherein said particular temporal constraint
2 object identifies said amount of time by identifying both members of the group consisting of
3 minimum and maximum times.

1 29. A medium according to claim 28, wherein said particular temporal constraint
2 object identifies said amount of time further by identifying a base time between said minimum
3 and maximum times.

1 30. A medium according to claim 23, wherein said database further includes a
2 disambiguation comment object associated with said particular temporal constraint object, said

3 disambiguation comment object identifying an operational uncertainty in a particular temporal
4 relationship identified in said temporal constraint object.

1 31. A medium according to claim 23, wherein said operational uncertainty comprises
2 an inconsistency in one of said temporal relationships as specified in said protocol.

1 32. A medium according to claim 23, wherein said operational uncertainty comprises
2 vagueness in one of said temporal relationships as specified in said protocol.

1 33. A medium according to claim 23, wherein said operational uncertainty comprises
2 omission of one of said temporal relationships from said protocol.

1 34. A method for evaluating a clinical trial protocol, comprising the steps of:
2 encoding workflow tasks of a clinical trial protocol into a database structured according
3 to a predetermined model, said model including slots predefined for describing respective
4 aspects of protocol events and slots predefined for describing temporal relationships among
5 protocol events, including amounts of time allowed between two or more protocol events; and
6 during said step of encoding, identifying an operational uncertainty in said protocol
7 regarding a particular one of said amounts of time.

1 35. A method according to claim 34, further comprising the step of displaying a
2 graphical-visual representation of said protocol, said graphical-visual representation including a

3 human-perceptible indication that said particular amount of time has an operational uncertainty
4 associated therewith.

1 36. A method according to claim 34, wherein said predetermined model comprises a
2 predetermined object class structure and said slots are organized into data objects defined by said
3 object class structure.

1 37. A method according to claim 36, wherein said data objects include protocol event
2 objects describing protocol events, and temporal constraint objects describing temporal
3 constraints among said protocol event objects, each of said temporal constraint objects including
4 at least one slot for identifying an amount of time allowed between two or more protocol events.

1 38. A method according to claim 37, further comprising the steps of:
2 instantiating a disambiguation data object defined according to said object class structure
3 describing said operational uncertainty; and
4 associating said disambiguation data object with a temporal constraint object which
5 includes a slot for identifying said particular amount of time.

1 39. A medium according to claim 34, wherein said operational uncertainty comprises
2 an inconsistency in said particular amount of time as specified in said protocol.

1 40. A medium according to claim 34, wherein said operational uncertainty comprises
2 vagueness in said particular amount of time as specified in said protocol.

1 41. A medium according to claim 34, wherein said operational uncertainty comprises
2 omission of said particular amount of time from said protocol.

1 42. A method for evaluating a clinical trial protocol, comprising the steps of:
2 encoding workflow tasks of a clinical trial protocol into a database that includes data
3 objects describing protocol events and relationships among protocol events;
4 identifying an operational uncertainty in said protocol during said step of encoding;
5 encoding said uncertainty into said database; and
6 in dependence upon said database, outputting a report setting forth the operational
7 uncertainties identified in said protocol and encoded into said database.

1 43. A method according to claim 42, further comprising the step of associating said
2 particular data object with at least one of said data objects in said database.

1 44. A method according to claim 43, wherein said data objects include protocol event
2 objects describing protocol events, and temporal constraint objects describing temporal
3 constraints among said protocol event objects,
4 and wherein said step of associating comprises the step of associating said particular data
5 object with one of said protocol event objects or one of said temporal constraint objects in said
6 database.

1 45. A method according to claim 42, wherein said database is an object-oriented
2 database.

1 46. A method according to claim 42, further comprising the step, prior to said step of
2 outputting, of sorting a list of said operational uncertainties identified in said protocol and
3 encoded into said database.

1 47. A method according to claim 42, wherein said step of outputting comprises the
2 step of outputting in tabular form the operational uncertainties identified in said protocol and
3 encoded into said database.

1 48. A method according to claim 42, wherein said operational uncertainty comprises
2 an inconsistency in said protocol.

1 49. A method according to claim 42, wherein said operational uncertainty comprises
2 an insufficiently specified parameter in said protocol.

1 50. A method according to claim 42, wherein said operational uncertainty comprises
2 an omitted parameter in said protocol.

1 51. A method according to claim 42, wherein said operational uncertainty concerns a
2 temporal constraint among at least two of said protocol events.